



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE



FROM: HQ AFMOA/SGPT
170 Luke Avenue, Suite 400
Bolling AFB DC 20332-5113

10 Dec 93

SUBJ: Department of Defense (DoD) Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects - SAMPLE MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH THE DEPARTMENT OF DEFENSE (DoD) REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS (32 CFR 219)

TO: Wilford Hall Medical Center/SGS (Col Cissik)
David Grant USAF Medical Center/SGI (Col Root)
Keesler Medical Center/SGS (Lt Col Calcote)
USAF Medical Center Scott/SGE (Mr. Rodney Deltgen)
Uniformed Services University of the Health Sciences (LTC Daniels)
USAF Medical Center Wright-Patterson (Lt Col Ebert)
Malcolm Grow USAF Medical Center (Dr. Neurock)
AL/CD (Col Jones)
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1. References:

a. Department of Defense, Title 32, Code of Federal Regulations, Part 219 (32 CFR 219), "Protection of Human Subjects" and "Protection of Human Subjects in DoD Supported Research," August 19, 1991.

b. Department of Health and Human Services Regulation "Protection of Human Subjects," (45 CFR 46) August 19, 1991.

c. DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research", January 7, 1983.

d. Air Force Policy Directive (AFPD) 40-4, "Clinical Investigation and Human Use in Medical Research, 28 April 1993.

e. Air Force Instruction (AFI) 40-402, The Use of Human Subjects in Research, Development, Test, and Evaluation - Guidance and Procedures, 1993, In Preparation.

f. AFI 40-403, Clinical Investigation in Medical Research - Guidance and Procedures, 1993, In Preparation.

g. Title 10 United States Code Part 980, Limitation on use of humans as experimental subjects.

2. HQ AFMOA/SGPT has been given designated authority in assuring the protection

of human subjects in research conducted or supported by, or under the auspices of DoD, including studies conducted outside the continental United States (OCONUS). Reference (b) Subpart A has been accepted by the DoD as the Common Federal Policy for the Protection of Human Subjects. The DoD Common Federal Policy for the Protection of Human Subjects is promulgated in reference (a).

3. Pursuant to HQ AFMOA/SGPT's responsibility, we have developed a **SAMPLE MULTIPLE PROJECT ASSURANCE** (MPA) (Atch 1) which we have modified from that used by the Office for Protection of Research Risks of the National Institutes of Health. In preparing this sample, we have attempted to include all of the elements necessary for compliance with the regulations. As your facility has multiple projects/protocols involving human subjects, you are required to provide a MPA to this office NLT 15 Jan 94. If you already have a MPA through Health and Human Services (HHS) or another federal agency, you must provide our office a copy of that assurance.

4. Your facility MPA should be drafted by the activity governing clinical investigations or RDT&E and certified by the facility commander for submission to HQ AFMOA/SGPT. HQ AFMOA/SGPT will review applications and assign a multiple project assurance number if all criteria have been appropriately addressed. The MPA Number will consist of an eight character alphanumeric code (i.e., DOD50003). Following issuance of the MPA for your facility, all future protocols involving human subjects (except exempt and minimal risk or those requiring a single project assurance from the NIH) should be submitted to HQ AFMOA/SGPT using the HHS Certification Form 310 (Atch 2) and with the following certifying statement in the transmission letter:

"I certify this protocol/proposal has been reviewed and approved by the _____ IRB on _____ (date) and meets all criteria as set forth in MPA Number _____."

5. Previously approved, ongoing protocols should be certified with a Form 310 forwarded to our office during revision, amendment, or as part of the annual review process.

6. If you have any questions, please do not hesitate to contact this office. My point of contact is Lt Col Dan Brown, DSN 297-5078 or (202) 767-5078.



GERALD J. MERRITT, Colonel, USAF, BSC
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Office of the Surgeon General

- 6 Atch
1. Sample Multiple Project Assurance
 2. Federal Register, Jun 91
 3. Belmont Report
 4. Title 10 USC 980
 5. IRB Membership Form
 6. Protocol Form 310